

## NIH Biosafety Level 1 (BL1) - (Large Scale)

These questions are based on the Biosafety Level 1 (BL1) - Large Scale section of the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, March 1996 edition, Appendix K-II and K-III.

Complete this section only if your laboratory does large scale research or production using large quantities (greater than 10 liters of culture) of viable organisms containing recombinant DNA molecules.

Please circle the response that best describes the facility in which work with select agents will be carried out.

**N.A. = not applicable. If you mark "N.A." , please provide a brief explanation below that item or on a separate page.**

### Appendix K-II. Good Large Scale Practice (GLSP)

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| Yes, No, N.A. | Appendix K-II-A. Institutional codes of practice shall be formulated and implemented to assure adequate control of health and safety matters.  |
| Yes, No, N.A. | Appendix K-II-B. Written instructions and training of personnel shall be provided to assure that cultures of viable organisms containing recombinant DNA molecules are handled prudently and that the work place is kept clean and orderly.  |
| Yes, No, N.A. | Appendix K-II-C. In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g., uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recombinant DNA molecules. Eating, drinking, smoking, applying cosmetics, and mouth pipetting shall be prohibited in the work area. |
| Yes, No, N.A. | Appendix K-II-D. Cultures of viable organisms containing recombinant DNA molecules shall be handled in facilities intended to safeguard health during work with microorganisms that do not require containment.  |
| Yes, No, N.A. | Appendix K-II-E. Discharges containing viable recombinant organisms shall be handled in accordance with applicable governmental environmental regulations.   |
| Yes, No, N.A. | Appendix K-II-F. Addition of materials to a system, sample collection, transfer of culture fluids within/between systems, and processing of culture fluids shall be conducted in a manner that maintains employee's exposure to viable organisms containing recombinant DNA molecules at a level that does not adversely affect the health and safety of employees.  |
| Yes, No, N.A. | Appendix K-II-G. The facility's emergency response plan shall include provisions for handling spills.  |

### Appendix K-III

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| Yes, No, N.A. | Appendix K-III-A. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Laboratory Director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained. |
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- Yes, No, N.A. Appendix K-III-B. Cultures of viable organisms containing recombinant DNA molecules shall be handled in a closed system (e.g., closed vessel used for the propagation and growth of cultures) or other primary containment equipment (e.g., biological safety cabinet containing a centrifuge used to process culture fluids) which is designed to reduce the potential for escape of viable organisms. Volumes less than 10 liters may be handled outside of a closed system or other primary containment equipment provided all physical containment requirements specified in Appendix G-II-A, Physical Containment Levels--Biosafety Level 1, are met.
- Yes, No, N.A. Appendix K-III-C. Culture fluids (except as allowed in Appendix K-III-D) shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant DNA molecules have been inactivated by a validated inactivation procedure. A validated inactivation procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recombinant DNA molecules.
- Yes, No, N.A. Appendix K-III-D. Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be conducted in a manner which minimizes the release of aerosols or contamination of exposed surfaces.
- Yes, No, N.A. Appendix K-III-E. Exhaust gases removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate air/HEPA filters or by other equivalent procedures (e.g., incineration) to minimize the release of viable organisms containing recombinant DNA molecules to the environment.
- Yes, No, N.A. Appendix K-III-F. A closed system or other primary containment equipment that has contained viable organisms containing recombinant DNA molecules shall not be opened for maintenance or other purposes unless it has been sterilized by a validated sterilization procedure. A validated sterilization procedure is one which has been demonstrated to be effective using the organism that will serve as the host for propagating the recombinant DNA molecules.
- Yes, No, N.A. Appendix K-III-G. Emergency plans required by Sections IV-B-2-b-(6), Institutional Biosafety Committee, and IV-B-3-c-(3), Biological Safety Officer, shall include methods and procedures for handling large losses of culture on an emergency basis.